

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
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V6

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/398,412 09/17/99 TIMANS

J DX0904K

HM12/1208

EXAMINER

DNAX RESEARCH INSTITUTE
901 CALIFORNIA AVENUE
PALO ALTO CA 94304-1104

PRASAD, S

ART UNIT PAPER NUMBER

1646

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RECEIVED

DATE MAILED:

12/08/00

DEC 12 2000

Patent Department

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Restriction

OFFICE ACTION DOCKET

ACTION: 1-8-2001

1 mo.

ACTION: _____

ACTION: _____

DUE : _____

EOL : _____

| | | | |
|------------------------------|------------------------|-----------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/398,412 | Timans, Jacqueline C. | |
| | Examiner | Art Unit | |
| | Sarada C Prasad | 1646 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) Interview Summary (PTO-413) Paper No(s) _____
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: _____

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-4, 6 are drawn to an isolated or recombinant IL-1 ζ polypeptide, classified in class 530, and subclass 351.

Group II. Claims 7-9, 19-20 are drawn to an antibody to IL-1 ζ polypeptide and a method of making an antibody to such, classified in class 530, subclass 389.2.

Group III. Claims 5, 10, 11-16 are drawn to an isolated or recombinant nucleic acid encoding an IL-1 ζ polypeptide, a method of its expression in a host cell, fusion protein, classified in class 435 and subclass 69.52.

Group IV. Claims 17-18 are drawn to a method of modulating a cell involved in an inflammatory response comprising contacting said cell with an agonist or antagonist of a primate IL-1 ζ polypeptide, classified in class 514, subclass 2.

These inventions in Groups I-IV are distinct, each from the other for the following reasons:

Inventions I, II and III are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. For example, polynucleotide of invention III can be used in a materially different processes such as: a probe for hybridization, making transgenic animals, in other diagnostic methods or gene therapy. The polypeptides of IL-1 ζ , in invention I, can be used to bind to agonist or antagonist which may be a protein or a small molecular ligand or an antibody molecule or portions of antibody molecules with improved binding characteristics. In a similar manner, the antibodies to the various IL-1 ζ

fragments, in invention II can be used in achieving several end points such as regulators of host responses to infection, immune responses, inflammation, and trauma.

Inventions in Group IV and Groups I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, invention of Group IV is drawn to a method of modulating inflammatory responses with agonist or antagonist of IL-1 ζ polypeptide. For example, inflammatory responses are mediated by lymphokines other than IL-1 ζ .

Inventions in Group III and Group I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case IL-1 ζ can be made by means other than what has been described in the instant invention of Group III. For example, IL-1 ζ and the variants can be synthesized by chemical means or isolation from relevant tissue.

These inventions I-IV are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classification. There are different issues for the search and examination of each would be unduly burdensome; therefore, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Art Unit: 1646

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarada C Prasad whose telephone number is 703-305-1009. The examiner can normally be reached Monday – Friday from 8.00 AM to 4.30 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sarada Prasad, Ph.D.
Examiner
Art Unit 1646
October 5, 2000

Prema Mertz
PREMA MERTZ
PRIMARY EXAMINER